Calendar No. 1018

100TH CONGRESS
2d Session

SENATE

REPORT
100-561

MEDICAL TESTING IMPROVEMENT ACT OF 1988

SEPTEMBER 29 (legislative day, SEPTEMBER 26), 1988.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2477]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2477) to amend the Public Health Service Act to modify the authority for the regulation of clinical laboratories to require licensed laboratories to qualify under proficiency testing programs, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

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I. SUMMARY OF THE BILL

S. 2477 amends the Public Health Service Act and makes additional provisions as follows:

1. *Licensing.*—Requires all clinical medical laboratories, including physician office laboratories, to be licensed by the Secretary of Health and Human Services, effective January 1, 1990. A few specific exemptions are allowed. Licenses will be issued for two years to laboratories meeting the requirements of the law.

2. *Self Referral.*—Prohibits a physician from referring laboratory work to a laboratory in which he or she has a direct financial interest. Exceptions exist in the following instances:

a. where the physician is performing laboratory work only for his own patients;

b. where the financial interest consists only of ownership of investment securities traded over a publicly regulated exchange;

c. laboratories located in designated rural or frontier areas; and

d. when the physician is referring work to a hospital laboratory in which he or she has an ownership interest.

3. *Direct Billing.*—Requires that all tests performed at the request of the physician be billed directly to the patient. This would prohibit physicians from marking up laboratory bills and is consistent with Medicare billing procedures.

4. *Accreditation.*—Allows the Secretary to approve the use of private nonprofit accrediting bodies to conduct inspections and certify that a laboratory complies with Federal standards.

5. *Standards.*—Requires the Secretary to promulgate standards to assure consistent performance by licensed laboratories. The standards will require laboratories to maintain quality assurance and quality control programs, maintain records and equipment and facilities necessary for effective operations, and employ individuals meeting qualifications necessary to assure minimal competency. Alternative standards based on the types of tests performed and testing methodologies employed are permitted.

6. *Proficiency Testing.*—Requires the Secretary to establish a proficiency testing program and mandates quarterly testing, where appropriate, for compliance with proficiency standards. Nonprofit private or State proficiency testing programs may be granted approved status. If a laboratory fails to comply with the proficiency testing standards, it must take steps to undertake training and obtain necessary technical assistance to meet the proficiency testing standards. Laboratories are prohibited from referring their proficiency testing samples to other laboratories for analysis. The results of proficiency testing shall be available to the public.

7. *Cytology Standards.*—Requires the Secretary to establish national standards for quality assurance in cytology services designed to assure valid and reliable results. The standards shall include workload limits for cytotechnologists, documentation of the number of hours devoted to screening cytological specimens and the number of specimens screened, periodic proficiency testing, and internal quality assurance programs.

8. *Inspections.*—Grants the Secretary the authority to make both announced and unannounced inspections to insure compliance.

9. *Enforcement and Sanctions.*—Gives the Secretary the authority to require a laboratory to take corrective action if it is in substantial noncompliance with the licensing provisions of the act as well as the authority to impose civil fines. Confers upon the Secretary the authority to seek injunctive relief when a laboratory is engaged in practices which present an imminent and serious risk to human health. Provides for suspension or revocation of license in

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the event of noncompliance, such suspensions being subject to judicial review.

10. *Fees.*—Provides for payment of fees for licenses and inspections.

11. *Information.*—Requires the Secretary to publish annual lists of laboratories that have been subject to various sanctions or penalties.

12. *Studies.*—Requires the Secretary to conduct five studies on the clinical laboratory testing process.

II. Background and Need for Legislation

The Nation's clinical laboratories are an increasingly important component of our health care system. Advances in medical technology have given physicians more ways to examine specimens of body tissues and fluids to gain information important to proper diagnosis and thereapy of diseases. Since many clinical decisions rest on the outcome of laboratory tests, the need for accuracy and reliability of test results is obvious.

Unfortunately, the present system for regulating the vast clinical laboratory industry cannot begin to provide the necessary assurances of quality. There are no uniform guidelines for all laboratories doing similar types of work. Instead, the current system offers a patchwork of inconsistent and overlapping standards that leaves some laboratories trying to comply with multiple layers of regulation and while others are free of any regulatory oversight.

Background on the current system

A clinical laboratory is a facility which examines and performs tests on specimens of tissue or fluids from the human body to assist in the diagnosis, prevention, or treatment of disease. Laboratories are found in hospitals, in independent facilities, and in many physician offices. An estimated 4 to 6.2 billion clinical tests are performed each year, resulting in an annual expenditure of $20 to 25 billion. About half of that cost is in hospital laboratories, with the other half divided approximately equally between independent and physician office laboratories.

The Health Care Financing Administration (HCFA) regulates laboratories under two separate programs. The Clinical Laboratory Improvement Act of 1967 (CLIA) requires that all laboratories that send specimens in interstate commerce be subject to regulation by the Federal Government. The Medicare program (Titel XVIII of the Social Security Act) requires that laboratories wishing to be certified to receive payment for services provided to Medicare and Medicaid patients meet quality standards established by the Secretary.

CLIA licensure and Medicare certification both require laboratories to meet certain minimal standards pertaining to personnel, quality control, and performance. Compliance with the standards is determined by periodic surveys conducted on HCFA's behalf by State health departments or in the case of hospital laboratories, by private accreditation bodies.

According to HCFA, over 12,000 laboratories are certified by Medicare, of which about about 4,500 are independent labs, 6,600 are in hospitals, and 900 are in other settings. There are 1,520 lab-

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oratories licensed under CLIA, of which 1,320 are also Medicare certified. An additional 519 laboratories perform interstate testing but are exempt from CLIA regulation by virtue of accreditation by the College of American Pathologists or licensure by the State of New York.

Physician office laboratories, numbering an estimated 100,000, are not regulated at all by the Federal Government (although high-volume labs will come under Medicare regulation beginning January 1, 1990). Some other categories of laboratories are also either unregulated or only minimally covered: laboratories not sending specimens in interstate commerce; small or infrequently operating laboratories; laboratories attached to free-standing surgery or emergency centers or health maintenance organizations; and mobile testing labs.

In addition to Federal regulation, many States have regulatory programs covering laboratories, but they vary considerably in the types of labs covered and in the elements they include. The General Accounting Office considers that a full regulatory program should include provisions for licensure, proficiency testing programs, quality control programs, personnel requirements and standards, and inspection authority. According to this definition, 48 States regulate hospital laboratories and 45 regulate independent labs, but only 16 States regulate physician office laboratories.

ISSUES OF CONCERN

Evidence has accumulated in the medical literature, the popular press, and in recent congressional hearings that the performance of many clinical laboratories is not what it should be to assure quality testing for all patients. Investigations have uncovered too many instances of sloppy lab work, poorly trained employees, and outright fraud, all in a climate of lax Federal oversight and enforcement of existing regulations. There are several areas in which standards need to be applied more broadly and enforced more tightly.

Federal enforcement of laboratories' compliance with existing regulations has been minimal. Serious deficiencies have been reported in communication between HCFA, HHS Regional Offices, the State survey agencies, and private accreditation bodies. Frequently, the Department has given little direction to the local bodies, and also has not required that information be reported back which would allow the Department to evaluate laboratory performance and take enforcement actions where necessary. Furthermore, the sanctions available under current law are not flexible enough to allow a range of responses according to the seriousness of deficiencies.

Proficiency testing for validation of a laboratory's performance is a key feature of any laboratory regulation scheme, and is required by both CLIA Medicare. The laboratory receives proficiency testing samples sent out by organizations such as the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB), or a State survey agency. The laboratory analyzes the specimens and returns the results to the proficiency testing organization for grading. The organization determines the acceptable limits of variation and reports the results to the laboragory.

Current proficiency testing programs, however, have many weaknesses. There is no national proficiency testing system and no uniformity among testing organizations in standards for acceptable performance. Therefore, labs accredited by different organizations may have to meet different standards. Some States consider 70 percent accuracy a passing score while others set 80 percent as passing. Nearly 65 percent of State survey agencies interviewed by the HHS Inspector General's office say lack of national standards poses significant quality assurance problems.

An additional problem with the proficiency testing process is that the samples received by the laboratories are rarely "blind", so the lab has the opportunity to treat the samples with a level of care not given to ordinary patient specimens. Some studies have compared laboratory performance on testing identical samples, one labeled as a proficiency testing sample and one labeled as a patient specimen; results showed consistent bias toward greater accuracy in the proficiency testing samples. Some labs have even been found to send out their proficiency testing samples to other laboratories for analysis.

Lack of a national proficiency testing system is of particular concern in the area of cytology, the examination of cells under a microscope to identify abnormalities which may indicate disease. Screening for cervical cancer through use of the Pap smear is the most common type of cytological examination. Accurate interpretation of a Pap smear slide depends upon several factors. The physician must collect an adequate sample and prepare the slide properly. The cytotechnologist must be well-trained in identifying abnormal cells and must have sufficient time to spend looking at each slide. A pathologist must be available to review suspicious results. A failure in any one of these factors may result in a "false-negative" report and possibly a missed cervical cancer.

Unfortunately, there is much evidence of seriously inadequate performance by laboratories doing cytological testing. The main problem stems from excessive technician workloads and the lack of continuing education programs for both technicians and physicians. It is not uncommon for technologists to be required to review as many as 200 to 300 slides in a 24-hour period, whereas, the guidelines from the American Society for Cytotechnology recommend no more than 80 in that period. Some technologists essentially do piecework for more than one laboratory to supplement their low wages, and may work with little or no supervision. Pap smear pricing is very competitive, and some laboratories offer artificially low prices on Paps to secure physicians' business on other more lucrative work. This practice can lead to a laboratory being reluctant to inform physicians that they have submitted inadequate samples for fear of losing referrals. The lack of a Federal proficiency testing requirement and other quality assurance standards for cytology may endanger the health of many American women.

Of relatively recent concern is the large volume of testing performed in physicians' offices. Advances in medical technology and instrumentation have enabled physicians to do more and more sophisticated testing in their own or their practice group's facilities. In many cases, this capability has distinct advantages for patient care, leading to more rapid and appropriate diagnosis and therapy.

Changes in health care economics have also encouraged more testing in physician offices. Physician office laboratories (POLs) are a rapidly expanding sector of the industry, with an estimated annual growth rate of 16 percent and a current census of about 100,000.

Under current law, POLs are exempt from Federal regulation; 16 States have some degree of regulation, but it is not uniform. Very few of these laboratories participate in voluntary proficiency testing programs, continuing education or training for employees, or to maintain any particular standards for qualifications of personnel or for record keeping. Various studies have found deficiencies in the performances of unregulated POLs, and have shown that licensed POLs perform better than unlicensed POLs. The absence of standards requiring supervisory personnel to have training in laboratory technology is particularly detrimental to quality lab work.

A final area of concern is the financial arrangements between physicians and laboratories. Direct billing to patients for laboratory services removes any incentive for physicians to order medically unnecessary tests or to direct their business to low-quality laboratories offering price breaks or kickbacks. Likewise, there have been instances where physicians who have ownership or other financial interests in a laboratory have made inappropriate referrals for laboratory services to the possible detriment of patients's health or finances.

III. Text of the Bill as Reported

[100th Cong., 2d Sess.]

A BILL To amend the Public Health Service Act to modify the authority for the regulation of clinical laboratories to require licensed laboratories to qualify under proficiency testing programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

[SECTION 1. SHORT TITLE; REFERENCES.

[(a) Short Title.—This Act may be cited as the "Medical Testing Improvement Act of 1988".

[(b) References.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.).

[SEC. 2. ANNUAL INSPECTIONS.

[The second sentence of section 353(d)(1) (42 U.S.C. 263a(d)(1)) is amended by inserting after "and services," the following: "shall require an annual inspection to assure compliance with such standards, and".

[SEC. 3. PROFICIENCY TESTING PROGRAMS.

[(a) In General.—Section 353(d) (42 U.S.C. 263a(d)(1)) is amended—

[(1) in the second sentence of paragraph (1)—

[(A) by striking out "and" at the end of clause (iii); and

[(B) by striking out clause (iv) and inserting in lieu thereof the following:

[“(iv) qualification under a proficiency testing program established by the Secretary in accordance with paragraph (2); and”;

[(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

[(3) by inserting after paragraph (1) the following new paragraph:

[“(2)(A) The proficiency testing program established by the Secretary under clause (iv) of the second sentence of paragraph (1) shall require that a laboratory be tested annually (or more frequently as the Secretary determines necessary) for each category of test that the laboratory is authorized to perform under its license.

[“(B) A laboratory shall not be considered to have qualified under the proficiency testing program unless it is determined under the program to have performed the tests in each category correctly. A laboratory shall not be determined to have performed a test correctly unless the results of the laboratory under such test fall within the predetermined criteria for acceptable performance for the methodologies in use. Such methodologies shall be established for such test by the National Bureau of Standards, in consultation with such agencies as the Secretary may designate.

[“(C) Not later than 1 year after the date of enactment of this paragraph, the Secretary, in consultation with appropriate professional organizations, shall develop and carry out—

[“(i) a system of testing the proficiency of a laboratory in the examination of gynecological smears by means of unannounced rescreening of slides examined by the laboratory; and

[“(ii) a system of testing the proficiency of individuals who examine gynecological smears by means of unannounced rescreening of slides examined by the personnel.

[“(D)(i) A laboratory shall maintain records concerning—

[“(I) the number of slides processed during each 24-hour period by each individual who examines gynecological smears;

[“(II) the number of hours worked during each 24-hour period by each such individual;

[“(III) the quantity of time spent during each 24-hour period by each such individual on tasks ancillary to actual microscopic examination of gynecological smears; and

[“(IV) the individual’s false negative rate, as determined by the rescreen required by clause (iv).

[“(ii) A laboratory shall maintain a separate record for each individual who examines gynecological smears.

[“(iii) A laboratory shall provide quarterly to the Secretary records required under this subparagraph.

[“(iv) For each individual who examines gynecological smears, the laboratory shall conduct a random rescreen of at least 10 percent (or such greater percent as the Secretary determines is necessary) of gynecological smears interpreted to be in a benign category, record the results of the rescreen, and report such results to the Secretary.

[“(v) If a gynecological smear is found to be in a suspicious or positive category, the laboratory shall report this finding to the Secretary, together with the result of any previous interpretations

of gynecological smears performed by the laboratory for the same individual.

[''(vi) A laboratory shall make records required under this subparagraph accessible for inspection by the Secretary at any time.

[''(vii) All gynecological smears shall be retained for not less than 5 years from the date of examination.

[''(E) The Secretary shall make available under section 552 of title 5, United States Code, the results of the proficiency testing program, and the information reported pursuant to subparagraph (D).

[''(F) The Secretary shall maintain a technical and staff capacity to provide training and technical assistance to laboratories requesting such service and to laboratories that do not qualify under the proficiency testing program.''.

[(b) CONTRACTING OUT.—Section 353(j) is amended by adding at the end the following new sentences: ''The proficiency testing program established by the Secretary under subsection (d) may include authority to have the testing performed by a private entity only if the entity meets minimum standards established by the Centers for Disease Control. The Secretary shall maintain the capacity to conduct such testing.''.

[SEC. 4. DIRECT BILLING OF PATIENTS.

[The second sentence of section 353(d)(1) (as amended by section 3(a)(1) of this Act) is further amended by adding at the end thereof the following new clause:

[''(v) direct billing of patients for each task performed by the laboratory.''.

[SEC. 5. LICENSE TERM.

[The first sentence of section 353(d)(3) (as redesignated by section 3(a)(2) of this Act) is further amended by striking out ''three years'' and inserting in lieu thereof ''1 year''.

[SEC. 6. FEES.

[Section 353(d)(4) (as redesignated by section 3(a)(2) of this Act) is further amended by striking out all after ''licenses'' and inserting in lieu thereof a period.

[SEC. 7. SCOPE.

[Section 353 (42 U.S.C. 263a) (as amended by section 3(b) of this Act) is further amended—

[(1) by striking out subsection (i); and

[(2) by redesignating subsections (j) through (l) as subsections (i) through (k), respectively.

[SEC. 8. ASSISTANCE TO STATES.

[Section 353(k) (as redesignated by section 7(2) of this Act) is further amended by adding at the end thereof the following new sentence: ''The Secretary shall make grants to such a State to assist the State in carrying out such laws.''.

[SEC. 9. EFFECTIVE DATE.

[(a) IN GENERAL.—Except as provided in subsection (b), this Act and the amendments made by this Act shall become effective on January 1, 1990.

[(b) SCOPE.—The amendments made by section 7 shall become effective on January 1, 1992.]

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Testing Improvement Act of 1988".

SEC. 2. LICENSING OF LABORATORIES.

Section 353 of the Public Health Service Act (42 U.S.C. 263a) is amended to read as follows:

"SEC. 353. LICENSING OF LABORATORIES.

"(a) DEFINITION.—As used in this section:

"(1) LABORATORY; CLINICAL LABORATORY.—The term 'laboratory' or 'clinical laboratory' means a facility or location for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

"(2) PHYSICIAN OFFICE LABORATORY.—The term 'physician office laboratory' means a facility owned and controlled by a fully licensed physician or group of physicians who practice medicine as members of a legally recognized partnership, corporation, or professional services corporation that provides any of the services referred to in paragraph (1) solely and exclusively for the benefit of the patients of such physician or group.

"(b) LICENSE REQUIREMENT.—

"(1) IN GENERAL.—Except as provided in paragraph (2), no person who uses any instrumentality of interstate commerce in the ordinary course of business may solicit or accept a specimen for laboratory examination or other procedures unless there is in effect for the laboratory a license issued by the Secretary under this section applicable to the category of examinations or procedures that includes such examinations or procedures.

"(2) EXEMPTIONS.—The Secretary shall exempt from the requirements of this section, physician office laboratories and other laboratories that, in the judgment of the Secretary, perform only—

"(A) tests approved by the Food and Drug Administration for home use;

"(B) tests employing methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible;

"(C) tests performed personally by a licensed physician; and

"(D) such other tests as the Secretary determines can be accurately performed in a physician office laboratory and that, if performed incorrectly, pose no reasonable risk of harm to the patient.

"(c) ISSUANCE AND RENEWAL OF LICENSES.—

"(1) IN GENERAL.—The Secretary may issue or renew a license for a laboratory only if the laboratory meets the requirements of subsection (d).

"(2) TERM.—A license issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

"(d) SPECIAL REQUIREMENTS FOR LICENSES.—

"(1) IN GENERAL.—A laboratory may be issued a license or have its license renewed only if—

"(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the accreditation body that accredited the laboratory submits) an application—

"(i) in such form and manner as the Secretary shall by regulation prescribe;

"(ii) that describes the characteristics of the testing performed by the laboratory including—

"(I) the number and types of tests performed;

"(II) the test methodologies employed; and

"(III) the qualifications (educational background, training, and experience) of the personnel performing the tests; and

"(iii) that contains such other information as the Secretary may require to determine compliance with this section;

"(B) the laboratory provides the Secretary—

"(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f); or

"(ii) with proof of accreditation under subsection (e);

"(C) the laboratory agrees to permit inspections by the Secretary under subsection (g);

"(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require;

"(E) the laboratory agrees to treat proficiency testing samples in the same manner it treats samples referred to it in the ordinary course of business;

"(F) except as provided in paragraph (2), the laboratory agrees not to provide services ordered by a physician if the physician or an immediate family member of the physician has an ownership or other financial interest in the laboratory or receives compensation from the laboratory;

"(G) the laboratory agrees not to bill for an examination or procedure on a patient—

"(i) the physician who ordered the examination or procedure or who referred the patient for the examination or procedure or such physician's practice group; or

"(ii) a laboratory in which—

"(I) the physician who ordered the examination or procedure or who referred the patient for the examination or procedure;

"(II) an immediate family member of such physician; or

"(III) the physician's practice group;

has an ownership or other financial interest; and

"(H) the laboratory agrees to disclose to a laboratory any ownership or other financial interest held by a physician, a group of physicians, or an immediate member of the family of the physician if such physician or group of physicians ordered an examination or procedure referred to such laboratory or referred a patient for an examination or procedure referred to such laboratory.

"(2) NONAPPLICABILITY OF FINANCIAL INTEREST BAR.—Paragraph (1)(F) shall not apply if—

"(A) the ownership or financial interest in a laboratory consists only of the ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments), as defined by the Secretary in regulations, that are traded over a publicly regulated exchange and were purchased on terms generally available to the public;

"(B) the laboratory performs tests and procedures only for patients of the physician who has the ownership or financial interest or for patients of a practice group that includes such a physician;

"(C) the laboratory is located in a rural or frontier area (as defined by the Secretary), the physician discloses to the patient in the manner prescribed by the Secretary the physician's ownership or financial interest, and the bill to the patient sets forth (separately from any other charges to the patient) the amount of the charge for laboratory services; or

"(D) the laboratory is owned by a hospital or a health maintenance organization (as defined by the Secretary) where the ordering physician has an ownership or financial interest in the hospital or health maintenance organization, except that this subparagraph shall not apply to an ownership or financial interest that is limited to the laboratory or another subsidiary, affiliate, or subdivision of the hospital or health maintenance organization that includes the laboratory.

"(e) ACCREDITATION.—

"(1) IN GENERAL.—A laboratory may be accredited for purposes of obtaining a license if the laboratory—

"(A) meets the standards of an approved accreditation body; and

"(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

"(2) APPROVAL AND WITHDRAWAL OF APPROVAL FOR ACCREDITATION.—

"(A) STANDARDS.—The Secretary may approve a private nonprofit organization to be an accreditation body for the accreditation of laboratories if the organization—

"(i) agrees to inspect a laboratory using inspectors qualified in the test methodologies performed in such laboratory before issuing an accreditation and thereafter with such frequency as is determined by the Secretary;

"(ii) applies standards that are equal to or more stringent than the standards issued by the Secretary under subsection (f);

"(iii) assures that standards continue to be met by the laboratory; and

"(iv) in the case of any laboratory accredited by the body that has had its accreditation denied, suspended, withdrawn, or revoked or that has had any other action taken against it, agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken with respect to its accreditation or against it.

An accreditation body that changes its standards shall notify the Secretary of the changes.

"(B) CRITERIA AND PROCEDURES.—The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the Secretary determines that the accreditation body does not meet the requirements of subparagraph (A). If an accreditation body has had its approval withdrawn by the Secretary, the body shall, within 10 days of the withdrawal, notify each laboratory accredited by the body of the withdrawal.

"(C) WITHDRAWAL OF LICENSE.—If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the license of any laboratory accredited by the body shall continue in effect for 60 days after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if the laboratory submits an application for accreditation or a license in a timely manner after receipt of the notification of the withdrawal of approval.

"(D) EVALUATION.—The Secretary shall evaluate annually the performance of each approved accrediting body by surveying a sufficient number of laboratories accredited by such body to allow a reasonable estimate of performance by such body and by such other means as the Secretary considers appropriate.

"(3) REPORT.—The Secretary shall annually prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report that describes the results of the evaluation conducted under paragraph (2)(D).

"(f) STANDARDS.—

"(1) IN GENERAL.—The Secretary shall issue standards to assure consistent performance by laboratories licensed under this section of valid and reliable laboratory examinations and procedures. Such standards shall require each laboratory licensed under this section—

"(A) to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the procedures and services of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and reporting of results;

"(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory;

"(C) in performing and carrying out its procedures and services, to use only personnel meeting such qualifications as the Secretary may establish with respect to the laboratory director and, as appropriate, supervisors and other professional and technical personnel, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications may be different on the basis of the type of examinations and procedures being performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures;

"(D) to qualify under a proficiency testing program established by the Secretary under paragraph (3); and

"(E) to meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable tests, procedures, and services.

"(2) ALTERNATIVE STANDARDS.—The Secretary may, in consultation with appropriate private organizations and public agencies, establish different standards than the standards established under paragraph (1) for a class of laboratories based on the tests performed and testing methodologies employed. In establishing such standards, the Secretary may take into consideration—

"(A) the number of steps involved;

"(B) the degree of independent judgment involved;

"(C) the amount of interpretation involved;

"(D) the difficulty of the calculations involved;

"(E) the type of instruments used;

"(F) the calibration and quality control requirements of the instruments used;

"(G) the type of training required to operate the instruments used in the testing methodology; and

"(H) such other factors as the Secretary considers relevant.

"(3) PROFICIENCY TESTING PROGRAM.—

"(A) IN GENERAL.—The Secretary, in consultation with appropriate private organizations and government agencies, shall establish a national proficiency testing program for laboratories licensed under this section. The program shall require that a licensed laboratory be tested—

"(i) for each examination and procedure for which it is licensed, except analytes for which the Secretary has determined that a proficiency test cannot reasonably be developed; and

"(ii) on a quarterly basis for such examinations and procedures, except where the Secretary determines for technical and scientific reasons that a particular analyte should be tested less frequently, but not less often than twice per year.

The Secretary shall establish national criteria for acceptable performance under the proficiency program. The criteria shall be established for all analytes and shall be uniform.

"(B) APPROVED PROFICIENCY TESTING PROGRAMS.—The Secretary shall grant approved status to such nonprofit private or State proficiency testing programs that the Secretary determines meet the requirements of this section. The Secretary shall withdraw the approved status of any program that no longer meets the requirements of this section.

"(C) FAILURE OF PROFICIENCY TESTING.—The Secretary may, in lieu of or in addition to actions authorized under subsection (h), (i), or (j), require any laboratory that fails to perform acceptably on an individual analyte or category of analytes to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficiency testing program.

"(D) REFERRAL OF PROFICIENCY TESTING SAMPLES.—Any laboratory that the Secretary determines knowingly and intentionally refers its proficiency testing samples to another laboratory for analysis shall have its licenses revoked for a minimum of 1 year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

"(E) PUBLICATION OF RESULTS.—The Secretary shall compile and publish the results of the proficiency testing program established by the Secretary under subparagraph (A), together with such other information as the Secretary determines necessary to aid in interpretation of the results.

"(4) NATIONAL STANDARDS FOR QUALITY ASSURANCE IN CYTOLOGY SERVICES.—

"(A) ESTABLISHMENT.—The Secretary shall establish national standards for quality assurance in cytology services designed to assure consistent performance by laboratories of valid and reliable cytological services.

"(B) STANDARDS.—The standards established under subparagraph (A) shall include—

"(i) the maximum number of cytology slides that any individual may screen in a designated period while maintaining a level of accuracy established by the Secretary;

"(ii) requirements that clinical laboratories maintain a record of the number of cytology slides screened during each 24-hour period by each cytologist who examines cytology slides;

"(iii) the number of hours devoted during each 24-hour period to screening cytology slides;

"(iv) criteria for requiring rescreening of cytological preparations, including random rescreening of cytology specimens determined to be in the benign category, focused rescreening of such preparations in high risk groups, and rescreening of all prior cytological specimens, if available, for each abnormal cytology result;

"(v) periodic confirmation and evaluation of the proficiency of cytotechnologists and pathologists involved in screening or interpreting cytological preparations, in-

cluding unannounced on-site proficiency testing of such cytotechnologists and pathologists, with such testing to take place, to the extent practicable, under normal working conditions;

"(vi) procedures for detecting inadequately prepared slides, notifying referring physicians of such slides, and assuring that no cytological diagnosis is rendered on such slides;

"(vii) requirements that all cytological screening be done on the premises of a laboratory that is licensed under this section;

"(viii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate; and

"(ix) standards requiring periodic inspection of cytology services by persons experienced in cytology.

"(g) INSPECTIONS.—

"(1) IN GENERAL.—The Secretary may, on an announced or unannouced basis, during normal business hours, enter and inspect laboratories licensed under this section. In conducting such inspections, the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection, the Secretary may copy any such material or require to it be submitted to the Secretary. An inspection under this paragraph may be made only on presenting identification to the owner, operator, or agent in charge of the laboratory being inspected.

"(2) COMPLIANCE WITH REQUIREMENTS AND STANDARDS.—The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f). Inspections of laboratories not accredited under subsection (e) shall be conducted on a biennial basis or more frequently as determined by the Secretary to be necessary to assure compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards.

"(h) INTERMEDIATE SANCTIONS.—

"(1) IN GENERAL.—If the Secretary determines that a laboratory licensed under this section no longer substantially meets the requirements for licensing, the Secretary may impose intermediate sanctions (for a period not to exceed 1 year) in lieu of the actions authorized by subsection (i).

"(2) TYPES OF SANCTIONS.—The intermediate sanctions that may be imposed under under paragraph (1) shall include—

"(A) directed plans of correction;

"(B) civil money penalties in an amount not to exceed $10,000 for each day of substantial noncompliance; and

"(C) payment for the costs of onsite monitoring.

"(3) ADMINISTRATION.—

"(A) PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1), the amounts of any penalties, and the severity of each of these penalties. Such procedures shall include notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition under paragraph (1) of intermediate sanctions.

"(B) CIVIL MONEY PENALTIES.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) (other than subsections (a) and (b) of such section) shall apply to a civil money penalty described in paragraph (2)(B) in the same manner as such section applies to a penalty or proceeding under subsection (a) of such section.

"(i) SUSPENSION, REVOCATION, AND LIMITATION.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the license of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

"(A) has been guilty of misrepresentation in obtaining the license;

"(B) has performed or attempted to perform or represented the laboratory as entitled to perform a laboratory procedure or category of procedures not authorized in the license;

"(C) has failed to comply with the standards with respect to laboratories prescribed by the Secretary under subsection (f);

"(D) has failed to comply with reasonable requests of the Secretary for any information or materials, or work on materials, the Secretary considers necessary to determine the laboratory's continued eligibility for its license or continued compliance with the Secretary's standards;

"(E) has refused a request of the Secretary or any Federal officer or employee duly designated by the Secretary for permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation; or

"(F) has violated or aided and abetted in the violation of this section or of any regulation promulgated under this section.

"(2) SUSPENSION WITHOUT HEARING.—If the Secretary determines that the failure of a laboratory to comply with the standards of the Secretary under subsection (f) presents an imminent and serious risk to human health or if a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1), the Secretary may suspend the license of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 4 months from the effective date of the suspension. A suspension under this paragraph shall stay in effect

until the decision of the Secretary made after the hearing under paragraph (1).

"(3) INELIGIBILITY TO OWN OR OPERATE LABORATORIES AFTER REVOCATION.—No person who has owned or operated a laboratory that has had its license revoked may, within 2 years of the revocation of the license, own or operate a laboratory. The license of a laboratory under this section that has been excluded from participation under the medicare program established under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

"(j) INJUNCTIONS.—Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to public health, the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. On a proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

"(k) JUDICIAL REVIEW.—

"(1) PETITION.—Any laboratory that has had its license suspended, revoked, or limited by any final action taken under subsection (i) may at any time within 60 days after the date of such action file a petition with the United States court of appeals for the circuit in which the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

"(2) ADDITIONAL EVIDENCE.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be adduced on the hearing in such manner and on such terms and conditions as the court may consider proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken. The Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the original action of the Secretary, with the return of such additional evidence.

"(3) JUDGEMENT OF COURT.—On the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

"(4) FINALITY OF JUDGEMENT.—The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States on certiorari or certification as provided in section 1254 of title 28, United States Code.

"(l) SANCTIONS.—

"(1) IN GENERAL.—Any person who willfully violates any provision of this section or any regulation promulgated under this section shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than 1 year, or a fine of not more than $10,000, or both such imprisonment and fine, except that if a person commits such a violation after a conviction under this paragraph has become final, such person shall be imprisoned for not more than 3 years or fined not more than $100,000, or both.

"(2) USE OF SPECIMENS PRODUCED BY UNLICENSED LABORATORIES.—Any person who solicits or accepts, directly or indirectly, a specimen knowing that a laboratory test or other laboratory procedure will be performed using such specimen by a laboratory that is required to have in effect a license issued under this section and that does not have such a license in effect, or that is not authorized by its license to perform such test or procedure, shall be subject to a fine of not more than $100,000, or imprisonment for not more than 1 year, or both.

"(3) FALSE STATEMENTS.—Any person who willfully engages in any false, fictitious, or fraudulent statement in order to obtain or maintain a license under this section or to prevent discovery of a violation of this section shall be subject to a fine of not more than $100,000, or imprisonment for not more than 1 year, or both.

"(m) FEES.—

"(1) IN GENERAL.—The Secretary shall require payment of fees for the issuance and renewal of licenses and fees for laboratory inspections, in such amounts as the Secretary may establish to carry out this section.

"(2) LICENSE FEES.—License fees imposed under paragraph (1) shall be sufficient to cover the costs of administering this section, including evaluating and monitoring approved proficiency testing programs and accrediting bodies, implementing and monitoring compliance with the requirements of this section, and fulfilling the reporting requirements of this section. The license fees shall be based on the dollar volume and scope of the testing being performed by the laboratory.

"(3) INSPECTION FEES.—Inspection fees imposed under paragraph (1) shall be sufficient to cover the costs of inspections conducted by the Secretary for laboratories that are not accredited by an approved accrediting body or licensed by an exempt State. Laboratories that are accredited by an approved accrediting agency, or licensed by an exempt State, shall not be required to pay the inspection fees, but shall be required to pay the license fees.

"(n) INFORMATION.—On April 1, 1990, and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year,

that the Secretary determines is useful in evaluating the performance of a laboratory, including—

"(1) a list of laboratories that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

"(2) a list of laboratories—

"(A) that have had their licenses revoked, suspended, or limited under subsection (i); or

"(B) that have been the subject of a sanction under subsection (l);

together with a statement of the reasons for the revocation, suspension, limitation, or sanction;

"(3) a list of laboratories subject to intermediate sanctions under subsection (h);

"(4) a list of laboratories against which the Secretary has taken action under subsection (j), together with a statement of the reasons for such action; and

"(5) a list of laboratories that have been excluded from participation under title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 et seq.).

The information to be compiled under paragraphs (1) through (5) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such information as is necessary to interpret the information compiled under such paragraphs.

"(o) DELEGATION.—In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay for the services or facilities in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

"(p) STATE LAWS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

"(2) MORE STRINGENT REQUIREMENTS.—If a State enacts a law relating to a matter covered by this section that provides for a requirement equal to or more stringent than a requirement of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.".

SEC. 3. STUDIES.

(a) STUDIES.—The Secretary of Health and Human Services, acting through the Public Health Service, shall conduct studies of—

(1) the validity, reliability, and accuracy of proficiency testing of clinical laboratories under section 353 of the Public Health Service Act (as amended by section 2 of this Act);

(2) the correlation between established standards for personnel employed in clinical laboratories and the accuracy and reli-

ability of the results of the tests performed by the laboratories that are subject to such standards;

(3) the correlation between internal quality assurance and quality control programs for clinical laboratories and the accuracy and reliability of the results of the tests performed by the laboratories;

(4) the extent and nature of problems in the diagnosis and treatment of patients caused by inaccurate laboratory test results; and

(5) the effect on laboratory test accuracy of errors in each of the components of the clinical testing process, including the communication between the attending physician and the clinical laboratory that is to conduct the tests, the selection of the tests to be performed, the limits applicable to the tests selected, the acquisition of the material to be tested, the transportation of the material to the laboratory, the storage of the material by the laboratory, the analysis of the material by the laboratory, and the reporting of the results by the laboratory.

(b) REPORTS.—Not later than May 1, 1990, the Secretary shall report to Congress on the results of the studies conducted under subsection (a).

SEC. 4. EFFECTIVE DATE.

(a) IN GENERAL.—Except as otherwise provided in this section, section 353 of the Public Health Service Act (as amended by section 2 of this Act) shall become effective on January 1, 1990.

(b) ENFORCEMENT.—Subsections (h), (i), (j), (k), and (l) of section 353 of the Public Health Service Act (as amended by section 2 of this Act) shall become effective on January 1, 1989.

(c) PERSONNEL QUALIFICATIONS; INSPECTIONS.—Subsections (f)(1)(C) and (g) of section 353 of such Act shall become effective on January 1, 1991.

(d) STUDIES.—Section 3 of this Act shall become effective on the date of enactment of this Act.

IV. COMMITTEE VIEWS, S. 2477

SCOPE OF REGULATION

The Committee has become increasingly aware that lack of quality assurance and quality control in the medical testing industry is pervasive. Many have argued that the existing regulations and the system for enforcing compliance is inadequate, but thousands of laboratories (including physician office laboratories) have been exempt from federal regulation, including all physician office laboratories. The literature clearly establishes that regulated laboratories perform more accurately than unregulated laboratories.

Currently, CLIA regulates only those laboratories which process specimens shipped across state lines, leaving many laboratories wholly unregulated or subject to spotty state regulation. To remedy this inadequacy, jurisdiction under the bill has been expanded to encompass all laboratories which utilize any of the instrumentalities of interstate commerce (telephone, mail, private courier services, etc.) in the ordinary course of business. It is the intention of

the Committee that jurisdiction under this act be expanded to the limits allowed by the commerce clause of the Constitution.

Thus, the Committee intends that all laboratories be subject to federal regulation under this legislation except those which perform only simple tests where the risk of inaccurate results is negligible and pose only a minimal risk of harm to the patient if performed incorrectly.

PHYSICIAN OFFICE LABORATORIES

The Committee is aware that physician office laboratories are a rapidly expanding part of the medical testing industry, with an estimated annual growth rate of 16%. The Inspector General of the Department of Health and Human Services estimates that there may be as many as 100,000 physician office laboratories in this country, accounting for up to 50% of the testing being done in the United States. These laboratories do not fall under any currently existing federal regulatory programs (although beginning in 1990, Medicare will regulate physician office laboratories performing more than 5000 tests).

While the Committee does not intend to discourage physicians from performing tests in their own laboratories, it does intend that there be assurances of high quality in these laboratories. A study submitted to DHHS by Michael Kenney in 1986, "The Final Report on Assessement of Clinical Laboratory Regulation" found that unregulated laboratories in physician and group practice offices consistently displayed lower accuracy and precision results than regulated laboratories. A study published in the Journal of the American Medical Association by Crawley, Belsey, Brock, and Baer (1986) has shown that, according to proficiency testing data, physician office laboratories in Idaho improved when quality assurance standards were imposed.

A report from the Inspector General of the Department of Health and Human Service echoed findings of serious deficiencies in quality in physician office laboratories. The most frequently cited problems were the use of untrained personnel to perform tests and a lack of basic quality control and quality assurance measures, including participation in proficiency testing programs.

While it has been argued by some that physician office laboratories should be permitted the opportunity to voluntarily participate in proficiency testing programs, it must be noted that fewer than 7% of such laboratories currently participate in these programs.

Thus, the Committee proposes that physician office laboratories be regulated no differently than other laboratories performing the same categories of tests. At the same time, the Committee does not wish to impose unnecessarily rigorous regulatory burdens on those laboratories, whether they are in doctors' offices or other sites, which perform only certain categories of tests. For this reason, the Committee proposes to exempt those laboratories that perform only those tests which meet certain strict criteria. For example, the tests must have been approved for home use by the Food and Drug Administration. They must employ methodologies so simple and accurate that the likelihood of erroneous results is negligible, and pose no reasonable risk of harm to the patient if performed incor-

rectly. One other category of tests included under the exemption would be those tests performed personally by a licensed physician. However, the Committee is aware that at present there are a limited number of tests for which misdiagnosed results would not potentially cause serious harm.

DIRECT BILLING

Under the current law, a physician may purchase laboratory services from a laboratory and then submit a bill to the patient or insurer which includes a significant mark-up over the actual charge from the laboratory for the services rendered. The cheaper the laboratory services the greater the potential profit for the physician. The Committee is concerned that this desire to increase profit, coupled with an inability to independently judge the quality of laboratory services, have driven too many physicians to poor quality, cut-rate laboratories.

The Committee believes that the primary criterion a physician should use in choosing a laboratory is the *quality* of laboratory services. By requiring that a laboratory bill a patient directly, the physician's financial stake in the transaction is eliminated. This may also eliminate incentives to over-utilize tests by ordering more than are medically necessary. It is the Committee's hope as well, however, that physicians concerned about the overall cost of medical care ill continue to negotiate for lower prices on their patients' behalf.

There is already substantial precedent for the enactment of a direct billing law. In 1984, Congress concluded that physician markups of laboratory fees were widespread and costly to the federal government. Thus, the Deficit Reduction Act of 1984 imposed a direct billing requirement for Medicare reimbursement for laboratory services. Also, several states have already enacted direct billing laws for all laboratory services.

The Committee does not intend to extend this provision to physicians who work at or for public or private non-profit clinics, or to the clinics themselves. These clinics, such as community health centers, migrant health centers, and family planning clinics, serve a significant proportion of low-income persons, and provide free or low-cost services to this medically underserved clientele. Further, the Committee intends that the direct billing provision not apply to health maintenance organizations, including individual practice associations, whose services are provided on a prepaid capitated basis.

SELF-REFERRAL

The bill addresses the problem of conflicts of interest on the part of referring physicians by prohibiting a laboratory from providing services to a physician in instances where the physician or an immediate family member of the physician has an ownership or financial interest in the laboratory or receives compensation from the laboratory. This broad prohibition does not apply in instances where the ownership or financial interest in the laboratory consists only of the ownership of investment securities that are traded over a publicly regulated exchange which are purchased on terms gener-

ally available to the public; where the laboratory performs services only for the patients of the physician with the ownership interest or patients of a group practice that includes the physician; where the laboratory is located in a rural or frontier area; or where the laboratory is owned by a hospital or health maintenance organization in which the physician has an ownership interest in the entity as a whole.

This provision was adopted in response to evidence received by the Committee indicating a proliferation of financial arrangements between laboratories and physicians which link physicians' financial interests to utilization patterns. Many of these arrangements are in the form of disguised inducements offered to physicians in return for referring patients to the laboratory. Others involve offerings of limited partnership interests to physicians who are in a position to refer large volumes of work to the laboratory.

The Committee is troubled by reports (mentioned below) which indicate that economic alliances between referring physicians and providers create a substantial risk of inducing overutilization and overpricing. This was documented in studies conducted by Blue Cross/Blue Shield of Michigan (1984), HCFA Region V (1983) and Michigan Medicaid (1981) which demonstrated that physician ownership of laboratory services resulted in two modification of the "normal" test-ordering pattern: (1) more tests are ordered; (2) more expensive tests are ordered.

The Committee notes with interest that the Institute of Medicine's prestigious Committee on Implications of For-Profit Enterprise in Health Care noted in their 1986 report on "For-Profit Enterprise in Health Care" determined that physicians' investments in facilities to which referrals are made "* * * should be regarded as unethical and unacceptable."

While the Committee acknowledges that there are specific instances in which so called "self-referral" arrangements do not give rise to any claim of improper referral, overutilization or overpricing, it is at loss to articulate any guiding ethical principles which preclude the possibility of abuse other than the outright prohibition urged by the Institute of Medicine.

ACCREDITATION

In obtaining a license, a laboratory would have the choice of dealing directly with the Department of Health and Human Services or dealing with a private accrediting agency approved for this purpose by the Secretary in accordance with subsection (e). A laboratory choosing to be accredited by a private accrediting agency would not be exempt from licensure; it would still have to submit the information required to obtain a license and sign the agreement with the Secretary covering the matter set forth in subsection (d), and it would still receive a license from the Secretary. However, the laboratory would not have to deal directly with the Secretary in the application or accreditation process. Rather, it would submit all of the required application materials to the accrediting agency which would forward to the Secretary, on the laboratory's behalf, proof of accreditation and the additional information and documentation required to obtain a license.

The bill sets forth the requirements that a private accrediting agency would have to meet in order to be approved by the Secretary for this purpose. It would also require the Secretary to promulgate regulations setting forth the criteria and procedures which the Secretary would use in making, withdrawing, or reinstating such approvals.

The central requirement which a private accrediting agency would have to meet in order to be approved would be that it has adopted standards for accreditation that are equal to, or more stringent than, those adopted by the Secretary under subsection (f). To be approved, the private accrediting agency must have standards covering each of the elements required for licensure, and the agency's standards must be as rigorous as those established by the Secretary.

With respect to the requirement that the accrediting agency compel its accredited laboratories to participate in a proficiency testing program meeting the requirements set forth in subsection (f) the Committee wants to make it clear that the private accrediting agency would not be required to administer the proficiency testing program itself. It could, as an alternative, require the laboratory to participate in a proficiency testing program administered by an independent private or public agency which meets the requirements established by the Secretary.

STANDARDS

The Committee heard testimony that many of the existing standards for clincial laboratory performance are inadequate or inappropriate. Where adequate standards do exist, they are frequently not enforced in such a way to ensure compliance. While much of the discretion for the development of standards in areas such as performance, personnel, quality assurance, quality control, proficiency testing and cytology has been left to the discretion of the Secretary, it is the Committee's intent that these standards should be significantly more rigorous that those which currently exist.

The Committee is aware that the absence of uniform standards means that there are not universally accepted benchmarks of quality on which laboratories can be judged. The Committee believes that the development of such standards should be the highest priority of the Secretary upon enactment of this legislation.

However, the Committee also recognizes that there is wide variation among the kinds of tests that clinical laboratories (including physician office laboratories) perform, and that not all of these tests require the same level of regulatory oversight. It is for this reason that the Committee has given the Secretary discretion to establish alternative standards for classes of laboratories based on the tests performed and the testing methodologies employed. However, the Committee also recognizes that there is wide variation among the kinds of tests that clinical laboratories (including physician office laboratories) perform, and that not all of these require the same level of regulatory oversight. It is for this reason that the Committee has given the Secretary discretion to establish alternative Standards for classes of laboratories based on the tests performed and the testing methodologies employed.

In granting this discretionary authority to the Secretary, the Committee recognizes the value of having the level of federal regulation imposed on laboratories be commensurate with the characteristics of testing performed in the laboratories, rather than on other criteria, such as the volume of testing or the test setting. Having the standards of licensure differentiate on the basis of tests performed and test methodologies employed in the burden on those laboratories serves two purposes. First, it reduces the regulatory burden on those laboratories that perform only tests employing simple test methodologies. Second, the model enables the Secretary to allocate enforcement and oversight resources more appropriately and efficiently, since the laboratories could be divided into distinct classes that are each subject to separate standards reflecting the types of testing performed in each class.

In establishing a system under this subsection, the Committee envisions a two-step process to be followed by the Secretary. First, the Secretary would categorize tests and test methodologies into designated levels based on the criteria enumerated in the bill. The Secretary would consult with appropriate private sector organizations and public agencies in developing this categorization. The Committee further anticipates that the Secretary would review the categories on an on-going basis, so that a particular test may be recategorized as the technology for performing it develops.

Second, the Secretary would establish classes of laboratories based on the highest level of test methodology employed in the laboratory. Each laboratory would be subject to the methodology- or test-specific requirements as conditions for licensure.

The Committee further intends that this alternative system of standards would, if implemented by the Secretary, be applicable to laboratories that are accredited by approved private sector accrediting bodies. An accrediting body may be approved by the Secretary to accredit all classes or only specific classes of laboratories established under this subsection, if the accrediting body applies standards that are equal to or more stringent than the standards issued by the Secretary for each class of laboratory that will be accredited by that organization.

PROFICIENCY TESTING

To maintain its license under this legislation, a laboratory would be required to participate successfully in a proficiency testing program that met standards established by the Secretary. The Committee believes that proficiency testing should be the central element in determining a laboratory's competence, as it provides a measure of actual performance on laboratory test procedures rather than only gauging the potential for accurate outcomes. While there is proficiency testing for some analytes mandated under current law, the Committee is aware that there have been serious problems with some of the existing proficiency testing programs and that no proficiency testing programs exist for some laboratory procedures, most notably pap smear screening. The Committee intends that this legislation strengthen and improve the current system of proficiency testing.

The Secretary would be required to consult with appropriate private organizations and government agencies in the development and implementation of appropriate standards and criteria. The Committee recognizes that achieving a consensus among these groups may be difficult and suggests that the Secretary consider developing an advisory committee from which a majority consensus might emerge. Regardless of the method the Secretary chooses, the Committee urges the Secretary to develop these standards in a timely manner.

The Committee has given the Secretary the authority to exempt those tests for which he has concluded that an appropriate proficiency test could not be reasonbly developed or implemented. An example of an appropriate exemption might include slides of organic material that cannot be uniformly produced in large volume. However, the Committee does not intend for the Secretary to exempt analytes from proficiency testing merely because such testing is not currently available or because it is difficult to obtain consensus on the best method of proficiency testing.

The standards for proficiency testing would include criteria, to be applied uniformly nationwide, for determining whether a laboratory has achieved an acceptable level of accuracy and reliability. These would include, first, an objective determination for each analyte of the acceptable range of variability in test results. Rather than simply accepting results that are within two (or more) standard deviations of the "true value", which is often the case today, the Secretary should set out, in advance of the distribution of proficiency testing samples, the acceptable range of variability. (The Secretary could conclude that the "true value" is appropriately determined by the mean of the values for laboratories participating or by submitting the samples to reference laboratories.) These acceptable ranges of variability should be established for all analytes as soon as practical and would be uniform for each analyte subject to proficiency testing, though separate criteria may be established for different types of proficiency testing materials. The Committee intends for the Secretary to develop more rigorous standards than have heretofore been adhered to in the industry as a whole.

A laboratory could satisfy its proficiency testing requirement by participating either in a program administered by the Secretary or in a program administered by a private, non-profit organization approved by the Secretary for this purpose. The bill would authorize the Secretary to approve programs administered by an accrediting agency or by other private, nonprofit organizations, if the programs met the standards and criteria discussed above.

The Secretary would be required to compile and publish the results of the proficiency testing program. The Committee does not expect the Secretary to compile the results for each laboratory each quarter, but rather to compile aggregate or cumulative data in some reasonable manner.

CYTOLOGY

When specimens are collected, prepared and analyzed correctly, the pap smear test is a highly effective diagnostic tool for the early detection of cervical cancer, which accounts for the loss of an esti-

mated 7,000 lives every year. However, the Committee received disturbing testimony indicating that far too many of these fatalities are attributable to pap smear results which fail to indicate the presence of pre-cancerous or cancereous condition. In too many instances, such errors are the result of overworked and undersupervised cytotechnologists charged with the crucial responsibility of examining and categorizing cervical slides.

In response to such concerns, this legislation would require the Secretary to develop specific quality assurance standards for cytology services.

One primary concern of the Committee was that individuals reading pap smear slides were under great pressure to read too many slides too quickly, with the result being an error rate that was unacceptably high. The Committee heard reports that cytologists were reading several times the number of slides recommended by professional societies, or working two or three jobs to earn additional salary.

Thus, the bill would require the Secretary to set a workload limit for the number of cytology slides an individual could screen in a designated period. While the Committee has given the Secretary flexibility to determine the designated period, it would suggest that this period not be so long as to render workload limits meaningless. For example, establishing a yearly workload limit makes it much more difficult to monitor ongoing, day to day workload.

Further, the laboratory must record the number of slides screened by each individual during each 24 hour period and the number of hours spent actually screening slides. The Committee intends that this data be available for inspection so that accurate and ongoing determination of a particular cytotechnologist's workload could be made.

The Committee also recognizes that the imposition of a workload limitation inherently fails to reflect the varying degrees of experience and expertise among cytotechnologists. This raises two concerns. The first is that the workload limit will become a floor, thereby forcing slower screeners to work above their optimal accuracy level. The second concern is that the workload limit may be seen as a ceiling forcing some cytotechnologists to work below their capacity for safe and reliable analysis. This situation could needlessly prolong the time it takes to process cervical slides. Thus, the Committee encourages the Secretary to explore the possibility of establishing alternative limits for cytotechnologists who have demonstrated an unusual capacity for accurate screening.

Laboratories are now required to engage in a random rescreen of 10% of cytological preparations determined to be negative in order to detect errors. Based on hearing testimony and subsequent investigations, however, the Committee believes that there are other methods which have a greater likelihood of detecting errors because they will include a higher number of positive specimens. These include random rescreening of benign specimens, focused rescreening of slides from patients at higher risk of cervical cancer, and rescreening of all prior cytological specimens available from patients found to have an abnormal cytological reading.

The Committee is extremely concerned that there is currently no requirement for cytology proficiency testing as a condition of licen-

sure. The Committee urges the Secretary to place the highest priority on the development of a proficiency testing program for cytology. This program should include unannounced onsite proficiency testing, with every effort being made to ensure that the cytologist reads the slides to the extent practicable, under the same conditions he or she is reading non-test slides.

One of the major problems identified with pap smear screening was that cytotechnologists were doing work at home where no quality control systems are feasible. Another significant problem was that laboratories were screening slides they knew to be improperly prepared by the patient's physician so that a valid reading was not possible. To deal with these problems, the standard would require that all slides be screened on the premises of a certified laboratory and that the laboratory comply with a procedure for detecting inadequately prepared slides, declining to provide a test result on such slides, and notifying the physician of the problem with the slide.

Finally, the Committee was made aware that those persons inspecting laboratory cytology services are not always trained or experienced in cytology. It is the Committee's intent that the Secretary ensure that such inspectors have the training necessary to enable them to make judgements about the quality of cytology services specifically.

INSPECTIONS

The bill authorizes the Secretary to conduct an inspection of any licensed laboratory to evaluate compliance with the requirements of the bill. It would also mandate that the Secretary inspect all nonaccredited laboratories and some proportion of accredited laboratories. The Committee expects the Secretary to have many of these inspections conducted on an unannounced basis, in order to observe the laboratory during typical operations, rather than under ideal circumstances arranged in preparation for an announced inspection. The Committee instructs the Secretary to take all necessary precautions to prevent the disclosure of confidential patient information revealed during the course of such inspections.

Inspection of nonaccredited laboratories would normally take place on a biennial basis. However, the Secretary could inspect a laboratory more frequently, if problems had been identified with the laboratory or if the nature of the testing performed by the laboratory was such that the Secretary concluded more frequent inspection was warranted to monitor accuracy and reliability. The Secretary is given more flexibility to determine the frequency of inspection necessary for accredited laboratories.

INTERMEDIATE SANCTIONS

This provision would authorize the Secretary to impose one or more sanctions on a laboratory which fails to substantially comply with the requirements of section 353. The intermediate sanctions include directed plans of correction, civil monetary penalties for each day of substantial noncompliance, and payment of the costs of onsite monitoring. The Committee recognizes the right of a labora-

tory to procedural due process when an action is taken to restrict or limit a laboratory's ability to conduct business.

The provision recognizes the need for the Secretary to have multiple and flexible tools at his disposal to deal with laboratories which are unable or unwilling to meet the requirements of this section. The Committee believes that, in some instances, quality assurance and, ultimately, patient health, may be sacrificed where the Secretary decides to forego enforcement action because bringing such an action may be impractical or. In such cases, the imposition of intermediate sanctions would afford a laboratory the means to correct problems in a timely manner while allowing it to remain operational.

The Committee notes that a directed plan of correction would be particularly appropriate where a laboratory is out of compliance with this section, but where imposition of such a sanction in lieu of revocation, suspension or limitation would not place the health of the patient in jeopardy. The Secretary may also wish to impose such sanctions where the laboratory has made a good faith effort to comply with the law. Such sanctions may be appropriate for certain proficiency testing, quality assurance, and quality control violations. By contrast, the imposition of daily fines for noncompliance might be used in instances where a financial incentive is needed to bring a laboratory into compliance. Finally, the payment of costs of onsite monitoring will allow the Secretary to recover costs from noncomplying laboratories, particularly where extra resources are required to compel enforcement.

SUSPENSION, REVOCATION AND LIMITATION

This provision is comparable to subsection (e) of current law. It would permit revocation, suspension or limitation of a license for essentially the same violations of the law as is the case under current law. However, it also contains several important additions, notably, the requirement that inspections occur during hours that the laboratory would normally be in operation and also making noncompliance with intermediate sanctions grounds for suspension, revocation or limitation of a license.

The bill also authorizes the Secretary to suspend or limit the license of a laboratory prior to holding a hearing if, in the Secretary's judgment, the laboratory's failure to comply with standards under subsection (f) present an immediate and serious risk to human health; if the laboratory refuses the Secretary permission to inspect the laboratory; or refuses the Secretary's request for information or materials needed to determine the laboratory's continued compliance with licensing requirements. In such instances, the bill would require the Secretary to afford the laboratory an opportunity for a hearing within 4 months of the resulting suspension or limitation. This does not mean that the hearing must be concluded, or necessarily started, within 4 months. Rather, it means that the laboratory has the right to demand that a hearing be commenced within the 4 month period. Such period may be extended upon the request of the laboratory.

The bill would also prohibit any person who has had his license revoked from owning or operating another laboratory for two years

from the date of the revocation. It would also prevent any laboratory which has been excluded under Medicare for violations of Title XVIII of the Social Security Act from operating a laboratory under the Clinical Laboratory Improvement Act during the period of exclusion. The Committee intends that an owner or operator whose conduct precipitated a revocation not be allowed to operate a laboratory during the period of revocation.

INJUNCTIONS

This provision is the same as subsection (f) of the current law, with minor changes. It would authorize the Secretary to seek a temporary injunction or retraining order to stop a laboratory from continuing any activity which constitutes a significant hazard to the public health. Although the bill places at the Secretary's disposal a variety of enforcement tools, the Committee recognizes that there may be circumstances in which the threat to the public health is significant and so imminent as to warrant immediate action. The rules and precedents generally applicable to injunction relief would be applicable here as well, so that the Secretary would have to persuade the court that such relief was appropriate.

Two minor changes are to substitute the word "significant hazard" for the words "imminent hazard", as the basis for injunctive relief, and to delete the words "licensed under this section". The first change is intended to make it clear that the threat must be significant in order to warrant injunctive relief. The second change would clarify that a laboratory posing serious threat to public health could not avoid Secretarial action because it was not licensed under this section.

SANCTIONS

This provision would establish criminal penalties for the willful violation of the requirements of the section and regulations promulgated thereunder. Under current law, the maximum penalty for each violation is one year in prison, or $1,000 fine, or both. There is no provision establishing higher penalties for subsequent convictions.

Inasmuch as this bill is intended to safeguard the health of patients, the Committee believes that willful violations of this section should be met with penalties sufficient to adequately punish and deter such conduct. The current penalties in the existing law, which were passed over two decades ago, do not meet that objective. Laboratories which willfully violate the law not only place the public health in jeopardy, but undermine confidence in the system of medical testing. The Committee believes that the broad array of sanctions included in this bill must include strong criminal penalties for laboratories which disregard the law.

Further, the Committee is concerned about recidivism and has included more severe penalties for repeat offenders to deter such conduct.

The bill would also add a section making it a crime, for any person who willfully makes or causes to be made any false, fictitious or fraudulent statement in order to obtain or maintain a license or to prevent discovery of a violation of the section.

FEES

This provision replaces current law, which establishes a fee of $125 for the issuance and renewal of a license. The Committee believes the current fee is unrealistically low, and in fact has not been collected since 1983 because the cost of collection was no longer justified.

The bill would require the Secretary to charge fees for license and inspection at levels necessary to cover the costs to the Department of Health And Human Services of carrying out this section. The regulatory requirments of the bill are essential to assuring high quality laboratory testing. With the scarcity of federal funds to carry out enforcement activities, the Committee has provided for the Secretary to obtain the costs of such activities from laboratories.

In establishing fees the Secretary would be required to develop a formula for a license fee to be paid by laboratories based on the scope and volume of testing performed. The Secretary would also be required to develop an inspection fee to be paid by those laboratories not accredited by an approved accrediting body or licensed by an exempt state.

Laboratories that participate in an approved accrediting program would not be required to pay any of the costs associated with inspection. The approved accrediting body is required to conduct inspections and therefore there are no costs to the Secretary for inspections of such accredited laboratories.

INFORMATION

This provision is designed to increase consumer knowledge about the quality of laboratory testing and to enhance their ability to choose a laboratory based on the quality of its performance. The bill would require the Secretary to compile, and make available to physicians and the general public, information which the Secretary determines is useful in evaluating the performance of laboratories.

The Committee recognizes the unique role that dissemination of accurate information can play in assuring quality. The release of such information would help physicians select laboratories on the basis of quality, and give consumers an opportunity to assess the performance of individual laboratores on an objective basis. It should also serve as a deterrent to laboratories violating standards.

The information released will reveal which laboratories bear close scrutiny because of deficiencies or legal violations sufficient to warrant enforcement actions. A laboratory on any of the enumerated lists would typically have already been affored an opportunity to contest the sanction and to appeal it. If appropriate, the Secretary could add further notations indicating those cases that were still under review or appeal.

STATE LAWS

This provision maintains current law which states that Federal rules and requirements do not preempt state laws enacted to assure the quality of laboratory testing unless inconsistent with federal requirements. It also allows the Secretary to exempt from

compliance with section 353 laboratories in states with laws equal to or more stringent than federal law.

STUDIES

This provision requires the Secretary, acting through the Public Health Service, to conduct studies on the link between various forms of regulation and the reliability and accuracy of test results; the extent and nature of problems in the diagnosis and treatment of patients caused by inaccurate tests results, and the effect on test accuracy of various stages of the testing process. The Committee expects the Secretary to utilize those agencies within the Public Health Service best equipped to conduct such inquiries.

This provision was necessitated by the relative dearth of empirically based studies in this area. The Committee expects that, given this lack of information, the Secretary will undertake or commission original research. The Committee is particularly interested not only in the effect of regulation on accuracy and reliability, but in the larger question of clinical relevance or accurate and reliable test, i.e., the extent to which accurate and reliable tests are required by diagnosticians and the extent to which deviation from accurate and reliable results affect diagnosis, treatment, and ultimately, patient health.

V. Committee Action

S. 2477 was considered by the Committee on August 10, 1988 and was reported favorably with the amendment in the nature of a substitute by unanimous vote.

VI. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, August 30, 1988.

Hon. Edward M. Kennedy,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget office has prepared the attached cost estimate for S. 2477, the Medical Testing Improvement Act of 1988, as ordered reported by the Senate Committee on Labor and Human Resources on August 10, 1988.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

C.G. Nuckols
(For James Blum, Acting Director).

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 2477.
2. Bill title: Medical Testing Improvement Act of 1988.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on August 10, 1988.
4. Bill purpose: To amend the Public Health Service Act to modify the authority for the regulation of clinical laboratories to

require licensed laboratoreis to qualify under proficiency testing programs.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1989	1990	1991	1992	1993
Clinical laboratory regulation:					
Estimated authorization level	(1)				
Estimated outlays					
Clinical laboratory study:					
Estimated Authorization Level	1.3				
Estimated Outlays	1.3				

[1] The clinical laboratory regulations provision will be funded through fees.

The costs of this bill fall within budget function 550.

Basis of estimate: The CBO assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

H.R. 5150 would require the Secretary of Health and Human Services (HHS) to regulate clinical laboratories. Regulation for laboratories would include licensure, inspections, and proficiency testing. Laboratories would be required to pay fees for the issuance and renewal of licenses, based on the dollar volume and scope of the testing performed by the laboratory. In addition, laboratories not accredited by an approved accrediting agency or licensed by an exempt state would be required to pay inspection fees. No additional costs to the Federal Government would result from this legislation; the fees charged would fund the costs of the regulation.

The bill would also require the Public Health Service (PHS) to conduct several studies on clinical laboratory performance. The studies would include proficiency testing performance, personnel standards, quality assurance, and laboratory errors and would be completed by May 1, 1990. Based on information provided by the PHS, the studies would cost an estimated $1.3 million.

6. Estimated cost to State and local government: None.

7. Estimate comparison: The CBO prepared an estimate for H.R. 5150, the Clinical Laboratory Improvements Act of 1988, on August 11, 1988, as ordered reported by the House Committee on Energy and Commerce. The House bill included the same provisions.

8. Previous CBO estimate: None.

9. Estimate prepared by: Lori Housman.

10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VII. Regulatory Impact Statement

The Committee has determined that there will be a minimal to moderate increase in the regulatory burden of paperwork as a direct result of this bill. Any increase in regulatory paperwork would come as a result of the responsibilities of inspection and accreditation of clinical laboratories.

VIII. Section-by-Section Analysis

S. 2477, "Medical Testing Improvement Act of 1988" as reported by the Committee on Labor and Human Resources

Section 1 of the bill cites the Act as the "Medical Testing Improvement Act of 1988."

Section 2 of the bill amends Section 353 of the Public Health Service Act ("Licensing of Laboratories"), rewriting the entire section.

Section 353(a). Definition

The terms "laboratory" or "clinical laboratory" and "physician office laboratory" are defined.

Section 353(b). License Requirement

Except as specifically exempted, no person who uses any instrumentality of interstate commerce in the ordinary course of business may solicit or accept a specimen for laboratory procedures without a license issued by the Secretary for that type of procedure. The exemptions cover laboratories that perform only (A) tests approved for home use; (B) extremely simple and accurate tests; (C) tests performed personally by a licensed physician; and (d) other tests that the Secretary determines can be accurately performed in a physician office laboratory and that would not harm the patient if performed inaccurately.

Section 353(c). Issuance and Renewal of Licenses

Licenses may be issued or renewed only for laboratories that meet the licensing requirements of section 353(d). The term of the license is two years.

Section 353(d). Special Requirements for Licenses

(1) In General. Requirements for issuance or renewal of a license include the following:

(A) The laboratory (or its accreditation body) must submit an application describing the testing performed by the laboratory, including the number and types of tests performed, the tests methodologies employed, and the qualifications of the personnel performing the tests.

(B) The laboratory must either provide satisfactory assurances that it will operate in accordance with regulatory standards, or provide proof of accreditation under section 353(e).

(C) The laboratory must agree to permit inspections under section 353(g).

(D) The laboratory must agree to make records available and submit reports to the Secretary.

(E) The laboratory must agree to treat proficiency testing samples in the same manner as ordinary patient samples.

(F) Except as provided in paragaph (2), the laboratory must agree not to provide services when a physician (or an immediate family member) has an ownership or other financial interest in the laboratory or receives compensation from the laboratory.

(G) The laboratory must agree to bill patients directly and not to bill either the ordering or referring physician, their immediate family members, or their practice groups.

(H) The laboratory must agree to disclose to other laboratories to which it may refer specimens or patients any financial interests held by referring physicians, their practice groups, or family members.

(2) Nonapplicability of Financial Interest Bar. Paragraph (1)(F) shall not apply if:

(A) the financial interest consists only of ownership of investment securities traded over a publicly regulated exchange;

(B) the laboratory performs tests only for the physician's or the practice group's own patients;

(C) the laboratory is located in a designated rural or frontier area, and the physician discloses the financial interest and separates the charges on the bill; or

(D) the laboratory is owned by a hospital or health maintenance organization in which the physician has a finanical interest is limited to the laboratory

Section 353(e). Accreditation

(1) In General. A laboratory may be accredited for purposes of obtaining a license if the laboratory meets the standards of an approved accreditation body and authorizes the body to submit required records to the Secretary or a designated State agency.

(2) Approval and Withdrawal of Approval for Accreditation.

(A) Standards. A nonprofit organization may be approved to be an accreditation body for the accreditation of laboratories if it agrees to use inspectors qualified in the appropriate test methodologies, applies standards at least as strict as Federal standards, assures that the laboratory continues to meet the standards, agree to notify the Secretary of any action it takes to deny or revoke a laboratory's accreditation, and agrees to notify the Secretary of any changes in its standards.

(B) Criteria and Procedures. The Secretary is required to promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval. Accreditation bodies are required to notify laboratories within ten days if their approval is withdrawn.

(C) Withdrawal of License. If an accreditation body loses its approval, the license of a laboratory accredited by it will continue for 60 days, or longer if the laboratory submits an application for accreditation.

(D) Evaluation. The Secretary is required to evaluate annually the performance of each approved accrediting body by surveying a sample of laboratories.

(3) Report. Results of the evaluation are to be reported annually to Congress.

Section 353(f). Standards

(1) In General. The Secretary is required to issue standards to assure consistent performance by laboratories. The standards will require each licensed laboratory to:

(A) maintain a quality assurance and quality control program, including proper collection, transportation, and storage of specimens and reporting of results;

(B) maintain proper records, equipment, and facilities;

(C) employ personnel who meet qualifications established by the Secretary, which may vary based on the type of tests performed and the consequences of erroneous results;

(D) qualify under a proficiency program; and

(E) meet other requirements as determined by the Secretary.

(2) Alternative Standards. The Secretary is permitted to establish different standards for a class of laboratories based on the tests performed and testing methodologies employed. Criteria to be considered include the complexity of the tests and the instruments used, the degree of judgment and interpretation involved, and the type of training required to perform the tests.

(3) Proficiency Testing Program.

(A) In General. The Secretary is required to establish a national proficiency testing program for laboratories. A laboratory will be tested quarterly for each procedure for which it is licensed, unless the Secretary determines otherwise. The Secretary must establish uniform national criteria for acceptable performance under the proficiency program.

(B) Approved Proficiency Testing Programs. The Secretary may grant approved status to nonprofit private or State proficiency testing programs that meet the requirements of this section, and may withdraw the approved status if the program no longer meets the requirements.

(C) Failure of Proficiency Testing. If a laboratory fails to perform acceptably, the Secretary, instead of taking stronger action, may require the laboratory to undertake training and obtain technical assistance to meet the requirements of the proficiency testing program.

(D) Referral of Proficiency Testing Samples. Any laboratory found to have referred proficiency testing samples to another laboratory for analysis will lose its license for at least one year and be subject to fines and penalties.

(E) Publication of Results. The Secretary is required to publish the results of the proficiency testing program, accompanied by interpretive information.

(4) National Standards for Quality Assurance in Cytology Services. The Secretary is required to establish national standards for quality assurance in cytology services. The standards will include workload limits on the number of slides that may be screened and the number of hours that technologists spend screening; criteria for rescreening specimens; periodic proficiency testing of cytotechnologists and pathologists; procedures concerning inadequately prepared slides; requirements that all cytological screening be done on the premises of the laboratory; requirements for the retention of cytology slides; and requirements for periodic inspection of cytology services.

Section 353(g). Inspections

The Secretary is given authority to conduct announced and unannounced inspections of laboratories to determine their compli-

ance with requirements and standards. The Secretary is granted access to all facilities, equipment, materials, records, and information necessary. Unaccredited laboratories are to be inspected biennally, and accredited laboratories as often as deemed necessary.

Section 353(h). Intermediate Sanctions

If a licensed laboratory no longer meets the requirements for licensing, the Secretary may impose intermediate sanctions for up to one year. Such sanctions may include directed plans of correction, fines of up to $10,000 per day of noncompliance, and payment for the costs of onsite monitoring. The Secretary is to develop and implement procedures relative to the sanctions, including opportunity for the laboratory to respond. Civil money penalties will be handled in the same manner as those for improperly filed medicare and medicaid claims.

Section 353(i). Suspension, Revocation and Limitation

(1) In General. A laboratory may have its license suspended, revoked, or limited if, after reasonable notice and opportunity for hearing, the Secretary finds that its owner or personnel have:

(A) been guilty of misrepresentation in obtaining the license;

(B) performed or advertised procedures not authorized in the license;

(C) failed to comply with prescribed laboratory standards;

(D) failed to provide information or materials requested by the Secretary for compliance determinations;

(E) refused permission for inspections; or

(F) violated this section or its implementing regulations.

(2) Suspension without Hearing. If the Secretary determines that a laboratory's noncompliance with standards presents an imminent and serious risk to human health, or if a laboratory fails to provide requested information or to cooperate with inspections, the Secretary may suspend the license before holding a hearing. The opportunity for a hearing shall be provided within four months, with the suspension remaining in effect until the Secretary's decision.

(3) Ineligibility to Own or Operate Laboratories after Revocation. No one who has owned or operated a laboratory that has had their license revoked may, within two years of the revocation, own or operate a laboratory. If a laboratory has been excluded from medicare participation because of quality problems, its license will be suspended during the exclusion period.

Section 353(j). Injunctions

The Secretary may seek an injunction against continuation of any activity by a laboratory that constitutes a significant hazard to public health.

Section 353(k). Judicial Review

A laboratory that has had its license suspended, revoked, or limited has 60 days in which to file a petition with the circuit court or appeals for judicial review of the action. The court will send a copy of the petition to the Secretary, and the Secretary will file the record on which the action was based. The laboratory can submit additional evidence which, if approved by the court, will be pre-

sented to the Secretary for possible reconsideration of the original action. The court has jurisdication to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The judgment of the court will be final, subject to review by the Supreme Court.

Section 353(l). Sanctions

Violation of this section or its implementing regulations is a misdemeanor punishable by imprisonment for up to one year, or a fine of not more than $10,000, or imprisonment for up to one year, or both.

Section 353(m). Fees

The Secretary shall require payment of fees for the issuance and renewal of licenses and fees for laboratory inspections. License fees shall be based on the dollar volume and scope of testing of the laboratory, and shall be high enough to cover the costs of administering this section, including proficiency testing programs, accreditation, monitoring compliance, and fulfilling reporting requirements. Inspection fees are to be paid only by laboratories not accredited by an approved accrediting body or licensed by an exempt State, and shall be high enough to cover the costs of inspections of such laboratories conducted by the Secretary.

Section 353(n). Information

The Secretary is required to make available to physicians and the general public an annual report, beginning April 1, 1990, containing information useful in evaluating the performance of laboratories. The report is to include a list of laboratories that have been convicted of fraud, abuse, false billings, or kickbacks; a list of laboratories which have been sanctioned or whose licenses have been revoked, suspended, or limited, together with the reasons; a list of laboratories subject to intermediate sanctions; a list of laboratories that have been enjoined from hazardous actions; and a list of laboratories that have been excluded from participation in medicare or medicaid.

Section 353(o). Delegation

The Secretary is authorized to use and pay for the services or facilities of any Federal or State or local public agency or nonprofit private organization as necessary.

Section 353(p). State Laws

States are free to enact laws relating to clinical laboratories as long as the laws are not inconsistent with this section or its regulations. If a State enacts a law whose requirements are equal to or more stringent than the requirements of this section or its regulations, the Secretary may exempt clinical laboratories in that State from compliance with this section.

Section 3 of the bill requires the Secretary to conduct various studies and report their results to Congress by May 1, 1990. The Secretary is to study:

(1) the validity, reliability, and accuracy and proficiency testing programs;

(2) the correlation between personnel standards and accuracy and relability of the laboratory test results;

(3) the correlation between internal quality assurance and quality control programs and the accuracy and reliability of laboratory test results;

(4) the extent and nature of problems in the diagnosis and treatment of patients caused by inaccurate laboratory test results; and

(5) the contribution to laboratory error of each step in the testing process, including physician-laboratory communication, test selection, technical limits of the tests, sample collection, transportation, storage and analysis, and reporting of results.

Section 4 of the bill sets the effective date of section 353 as January 1, 1990. The subsections on enforcement, subsections (h) through (l), will become effective January 1, 1989. The subsections on personnel qualifications and inspections, subsections (f)(1)(C) and (g), will become effective on the date of enactment of this Act.

IX. Changes in Existing Law

In compliance with rule XXVI, paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

Part A—Research and Investigation

in general

* * * * * * *

Subpart 2—Clinical Laboratories

licensing of laboratories

[Sec. 353. (a) As used in this section—

[(1) the term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, man;

[(2) The term "interstate commerce" means trade, traffic, commerce, transportation, transmission, or communication between any State or possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

[(b)(1) No person may solicit or accept in interstate commerce, directly or indirectly, any specimen for laboratory examination or other laboratory procedures, unless there is in effect a license for such laboratory issued by the Secretary under this section applicable to such procedures.

[(2) The Secretary shall by regulation exempt from the provisions of this section laboratories whose operations are so small or infrequent as not to constitute a significant threat to the public health.

[(c) A license issued by the Secretary under this section may be applicable to all laboratory procedures or only to specified laboratory procedures or categories of laboratory procedures.

[(d)(1) A license shall not be issued in the case of any clinical laboratory unless (A) the application therefor contains or is accompanied by such information as the Secretary finds necessary, and (B) the applicant agrees and the Secretary determines that such laboratory will be operated in accordance with standards found necessary by the Secretary to carry out the purposes of this section. Such standards shall be designed to assure consistent performance by the laboratories of accurate laboratory procedures and services, and shall include, among others, standards to assure—

[(i) maintenance of a quality control program adequate and appropriate for accuracy of the laboratory procedures and services;

[(ii) maintenance of records, equipment, and facilities necessary for proper and effective operation of the laboratory;

[(iii) qualifications of the director of the laboratory and other supervisory professional personnel necessary for adequate and effective professional supervision of the operation of the laboratory (which shall include criteria relating to the extent to which training and experience shall be substituted for education); and

[(iv) participation in a proficiency testing program established by the Secretary.

[(2) A license issued under this section shall be valid for a period of three years, or such shorter period as the Secretary may establish for any clinical laboratory or any class or classes thereof; and may be renewed in such manner as the Secretary may prescribe. The provisions of this section requiring licensing shall not apply to a clinical laboratory in a hospital accredited by the Joint Commission on the Accreditation of Hospitals or by the American Osteopathic Association, or a laboratory which has been inspected and accredited by such commission or association, by the Commission on Inspection and Accreditation of the College of American Pathologists, or by any other national accreditation body approved for the purpose by the Secretary, but only if the standards applied by such commission, association, or other body in determining whether or not to accredit such hospital or laboratory are equal to or more stringent than the provisions of this section and the rules and regulations issued under this section, and only if there is adequate provision for assuring that such standards continue to be met by such hospital or laboratory; provided that any such laboratory shall be treated as a licensed laboratory for all other purposes of this section.

[(3) The Secretary may require payment of fees for the issuance and renewal of licenses, but the amount of any such fee shall not exceed $125 per annum.

[(e) A laboratory license may be revoked, suspended, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

[(1) has been guilty of misrepresentation in obtaining the license;

[(2) has engaged or attempted to engage or represented himself as entitled to perform any laboratory procedure or category of procedures not authorized in the license;

[(3) has failed to comply with the standards with respect to laboratories and laboratory personnel prescribed by the Secretary pursuant to this section;

[(4) has failed to comply with reasonable requests of the Secretary for any information or materials, or work on materials, he deems necessary to determine the laboratory's continued eligibility for its license hereunder or continued compliance with the Secretary's standards hereunder;

[(5) has refused a request of the Secretary or any Federal officer or employee duly designated by him for permission to inspect the laboratory and its operations and pertinent records at any reasonable time; or

[(6) has violated or aided and abetted in the violation of any provisions of this section or of any rule or regulation promulgated thereunder.

[(f) Whenever the Secretary has reason to believe that continuation of any activity by a laboratory licensed under this section would constitute an imminent hazard to the public health, he may bring suit in the district court for the district in which such laboratory is situated to enjoin continuation of such activity and, upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this section shall be granted without bond or by such court.

[(g)(1) Any party aggrieved by any final action taken under subsection (e) of this section may at any time within sixty days after the date of such action file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for judicial review of such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

[(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The

Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

[(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

[(4) The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final subject to review by the Supreme Court of the United States upon cetiorari or certification as provided in section 1254 of title 28, United States Code.

[(h) Any person who willfully violates any provision of this section or any rule or regulation promulgated thereunder shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of nor more than $1,000, or both such imprisonment and fine.

[(i) the provisions of this section shall not apply to any clinical laboratory operated by a licensed physician, osteopath, dentist, or podiatrist, or group thereof, who performs or perform laboratory tests on procedures, personally or through his or their employees, solely as an adjunct to the treatment of his or their own patients; nor shall such provisions apply to any laboratory with respect to tests or other procedures made by it for any person engaged in the business of insurance if made solely for purposes of determining whether to write an insurance contract or of determining eligibility or continued eligibility for payments thereunder.

[(j) In carrying out his functions under this section, the Secretary is authorized, pursuant to agreement, to utilize the service or facilities of any Federal or State or local public agency or nonprofit private agency or organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as he may determine.

[(k) Nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with the provisions of this section or with the rules and regulations issued under this section.

[(l) Where a State has enacted or hereafter enacts laws relating to matters covered by this section, which provide for standards equal to or more stringent than the provisions of this section or than the rules and regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this Section.

SEC. 353. LICENSING OF LABORATORIES.

(a) DEFINITION.—As used in this section:

(1) LABORATORY; CLINICAL LABORATORY.—The term 'laboratory' or 'clinical laboratory' means a facility or location for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathologi-

cal, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human begins.

(2) PHYSICIAN OFFICE LABORATORY.—The term 'physician office laboratory' means a facility owned and controlled by a fully licensed physician or group of physicians who practice medicine as members of a legally recognized partnership, corporation, or professional services corporation that provides any of the services referred to in paragraph (1) solely and exclusively for the benefit of the patients of such physician or group.

(b) LICENSE REQUIREMENT.—

(1) IN GENERAL.—Except as provided in paragraph (2), no person who uses any instrumentality of interstate commerce in the ordinary course of business may solicit or accept a specimen for laboratory examination or other procedure unless there is in effect for the laboratory a license issued by the Secretary under this section applicable to the category of examinations or procedures that includes such examinations or procedures.

(2) EXEMPTIONS.—The Secretary shall exempt from the requirements of this section, physician office laboratories and other laboratories that, in the judgment of the Secretary, perform only—

(A) tests approved by the Food and Drug Administration for home use;

(B) tests employing methodologies that are so simple and accurate as to render the likelihood or erroneous results negligible;

(C) tests performed personnally by a licensed physician; and

(D) such other tests as the Secretary determines can be accurately performed in a physician office laboratory and that, if performed incorrectly, pose no reasonable risk of harm to the patient.

(c) ISSUANCE AND RENEWAL OF LICENSES.—

(1) IN GENERAL.—The Secretary may issue or renew a license for a laboratory only if the laboratory meets the requirements of subsection (d).

(2) TERM.—A license issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

(d) SPECIAL REQUIREMENTS FOR LICENSES.—

(1) IN GENERAL.—A laboratory may be issued a license or have its license renewed only if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the accreditation body that accredited the laboratory submits) an application—

(i) in such form and manner as the Secretary shall by regulation prescribe;

(ii) that describes the characteristics of the testing performed by the laboratory including—

(I) the number and types of tests performed;

(II) the test methodologies employed; and

(III) the qualifications (educational background, training, and experience) of the personnel performing the test; and

(iii) that contains such other information as the Secretary may require to determine compliance with this section;

(B) the laboratory provides the Secretary—

(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f); or

(ii) with proof of accreditation under subsection (e);

(C) the laboratory agrees to permit inspections by the Secretary under subsection (g);

(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require;

(E) the laboratory agrees to treat proficiency testing samples in the same manner it treats samples referred to it in the ordinary course of business;

(F) except as provided in paragraph (2), the laboratory agrees not to provide services ordered by a physician if the physician or an immediate family member of the physician has an ownership or other financial interest in the laboratory or receives compensation from the laboratory;

(G) the laboratory agrees not to bill for an examination or procedure on a patient—

(i) the physician who ordered the examination or procedure or who referred the patient for the examination or procedure or such physician's practice group; or

(ii) a laboratory in which—

(I) the physician who ordered the examination or procedure or who referred the patient for the examination or procedure;

(II) an immediate family member of such physician; or

(III) the physician's practice group;

has an ownership or other financial interest; and

(H) the laboratory agrees to disclose to a laboratory any ownership or other financial interest held by a physician, a group of physicians, or an immediate member of the family of the physician if such physician or group of physicians ordered an examination or procedure referred to such laboratory or referred a patient for an examination or procedure referred to such laboratory.

(2) NONAPPLICABILITY OF FINANCIAL INTEREST BAR.—Paragraph (1)(F) shall not apply if—

(A) the ownership or financial interest in a laboratory consists only of the ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments), as defined by the Secretary in regulations, that are traded over a publicly regulated exchange and were purchased on terms generally available to the public;

(B) the laboratory performs tests and procedures only for patients of the physician who has the ownership or finan-

cial interest or for patients of a practice group that includes such a physician;

(C) the laboratory is located in a rural or frontier area (as defined by the Secretary), the physician discloses to the patient in the manner prescribed by the Secretary the physician's ownership or financial interest, and the bill to the patient sets forth (separately from any other charges to the patient) the amount of the charge for laboratory services; or

(D) the laboratory is owned by a hospital or a health maintenance organization (as defined by the Secretary) where the ordering physician has an ownership or financial interest in the hospital or health maintenance organization, except that this subparagraph shall not apply to an ownership or financial interest that is limited to the laboratory or another subsidiary, affiliate, or subdivision of the hospital or health maintenance organization that includes the laboratory.

(e) ACCREDITATION.—

(1) IN GENERAL.—A laboratory may be accredited for purposes of obtaining a license if the laboratory—

(A) meets the standards of an approved accreditation body; and

(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

(2) APPROVAL AND WITHDRAWAL OF APPROVAL FOR ACCREDITATION.—

(A) STANDARDS.—The Secretary may approve a private nonprofit organization to be an accreditation body for the accreditationl of laboratories if the organization—

(i) agrees to inspect a laboratory using inspectors qualified in the test methodologies performed in such laboratory before issuing an accreditation and thereafter with such frequency as is determined by the Secretary;

(ii) applies standards that are equal to or more stringent than the standards issued by the Secretary under subsection (f);

(iii) assures that standards continue to be met by the laboratory; and

(iv) in the case of any laboratory accredited by the body that has had its accreditation denied, suspended, withdrawn, or revoked or that has had any other action taken against it, agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken with respect to its accreditation or against it.

An accreditation body that changes its standards shall notify the Secretary of the changes.

(B) CRITERIA AND PROCEDURES.—The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the Secretary determines that the accreditation body does not meet

the requirements of subparagraph (A). If an accreditation body has had its approval withdrawn by the Secretary, the body shall, within 10 days of the withdrawal, notify each laboratory accredited by the body of the withdrawal.

(C) WITHDRAWAL OF LICENSE.—If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the license of any laboratory accredited by the body shall continue in effect for 60 days after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if the laboratory submits an application for accreditation or a license in a timely manner after receipt of the notification of the withdrawal of approval.

(D) EVALUATION.—The Secretary shall evaluate annually the performance of each approved accrediting body by surveying a sufficient number of laboratories accredited by such body to allow a reasonable estimate of performance by such body and by such other means as the Secretary considers appropriate.

(3) REPORT.—The Secretary shall annually prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report that describes the results of the evaluation conducted under paragraph (2)(D).

(f) STANDARDS.—

(1) IN GENERAL.—The Secretary shall issue standards to assure consistent performance by laboratories licensed under this section of valid and reliable laboratory examinations and procedures. Such standards shall require each laboratory licensed under this section—

(A) to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the procedures and services of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and reporting of results;

(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory;

(C) in performing and carrying out its procedures and services, to use only personnel meeting such qualifications as the Secretary may establish with respect to the laboratory director and, as appropriate, supervisors and other professional and technical personnel, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications may be different on the basis of the type of examinations and procedures being performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures;

(D) to qualify under a proficiency testing program established by the Secretary under paragraph (3); and

(E) to meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable tests, procedures, and services.

(2) ALTERNATIVE STANDARDS.—The Secretary may, in consultation with appropriate private organizations and public agencies, establish different standards than the standards established under paragraph (1) for a class of laboratories based on the tests performed and testing methodologies employed. In establishing such standards, the Secretary may take into consideration—

(A) the number of steps involved;

(B) the degree of independent judgment involved;

(C) the amount of interpretation involved;

(D) the difficulty of the calculations involved;

(E) the type of instruments used;

(F) the calibration and quality control requirements of the instruments used;

(G) the type of training required to operate the instruments used in the testing methodology; and

(H) such other factors as the Secretary considers relevant.

(3) PROFICIENCY TESTING PROGRAM.—

(A) IN GENERAL.—The Secretary, in consultation with appropriate private organizations and government agencies, shall establish a national proficiency testing program for laboratories licensed under this section. The program shall require that a licensed laboratory be tested—

(i) for each examination and procedure for which it is licensed, except analytes for which the Secretary has determined that a proficiency test cannot reasonably be developed; and

(ii) on a quarterly basis for such examinations and procedures, except where the Secretary determines for technical and scientific reasons that a particular analyte should be tested less frequently, but not less often than twice per year.

The Secretary shall establish national criteria for acceptable performance under the proficiency program. The criteria shall be established for all analytes and shall be uniform.

(B) APPROVED PROFICIENCY TESTING PROGRAMS.—The Secretary shall grant approved status to such nonprofit private or State proficiency testing programs that the Secretary determines meet the requirements of this section. The Secretary shall withdraw the approved status of any program that no longer meets the requirements of this section.

(C) FAILURE OF PROFICIENCY TESTING.—The Secretary may, in lieu of or in addition to actions authorized under subsection (h), (i), or (j), require any laboratory that fails to perform acceptably on an individual analyte or category of analytes to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficiency testing program.

(D) REFERRAL OF PROFICIENCY TESTING SAMPLES.—Any laboratory that the Secretary determines knowingly and intentionally refers its proficiency testing samples to another laboratory for analysis shall have its licenses revoked for a

minimum of 1 year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

(E) PUBLICATION OF RESULTS.—The Secretary shall compile and publish the results of the proficiency testing program established by the Secretary under subparagraph (A), together with such other information as the Secretary determines necessary to aid in interpretation of the results.

(4) NATIONAL STANDARDS FOR QUALITY ASSURANCE IN CYTOLOGY SERVICES.—

(A) ESTABLISHMENT.—The Secretary shall establish national standards for quality assurance in cytology services designed to assure consistent performance by laboratories of valid and reliable cytological services.

(B) STANDARDS.—The standards established under subparagraph (A) shall include—

(i) the maximum number of cytology slides that any individual may screen in a designated period while maintaining a level of accuracy established by the Secretary;

(ii) requirements that clinical laboratories maintain a record of the number of cytology slides screened during each 24-hour period by each cytologist who examines cytology slides;

(iii) the number of hours devoted during each 24-hour period to screening cytology slides;

(iv) criteria for requiring rescreening of cytological preparations, including random rescreening of cytology specimens determined to be in the benign category, focused rescreening of such preparations in high risk groups, and rescreening of all prior cytological specimens, if available, for each abnormal cytology result;

(v) periodic confirmation and evaluation of the proficiency of cytotechnologists and pathologists involved in screening or interpreting cytological preparations, including unannounced on-site proficiency testing of such cytotechnologists and pathologists, with such testing to take place, to the extent practicable, under normal working conditions;

(vi) procedures for detecting inadequately prepared slides, notifying referring physicians of such slides, and assuring that no cytological diagnosis is rendered on such slides;

(vii) requirements that all cytological screening be done on the premises of a laboratory that is licensed under this section;

(viii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate; and

(ix) standards requiring periodic inspection of cytology services by persons experienced in cytology.

(g) INSPECTIONS.—

(1) IN GENERAL.—The Secretary may, on an announced or unannounced basis, during normal business hours, enter and inspect laboratories licensed under this section. In conducting

such inspections, the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection, the Secretary may copy any such material or require to it be submitted to the Secretary. An inspection under this paragraph may be made only on presenting identification to the owner, operator, or agent in charge of the laboratory being inspected.

(2) COMPLIANCE WITH REQUIREMENTS AND STANDARDS.—The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f). Inspections of laboratories not accredited under subsection (e) shall be conducted on a biennial basis or more frequently as determined by the Secretary to be necessary to assure compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards.

(h) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a laboratory licensed under this section no longer substantially meets the requirements for licensing, the Secretary may impose intermediate sanctions (for a period not to exceed 1 year) in lieu of the actions authorized by subsection (i).

(2) TYPES OF SANCTIONS.—The intermediate sanctions that may be imposed under under paragraph (1) shall include—

(A) directed plans of correction;

(B) civil money penalties in an amount not to exceed $10,000 for each day of substantial noncompliance; and

(C) payment for the costs of onsite monitoring.

(3) ADMINISTRATION.—

(A) PROCEDURES.—The Secretary shall be develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1), the amounts of any penalties, and the severity of each of these penalties. Such procedures shall include notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition under paragraph (1) of intermediate sanctions.

(B) CIVIL MONEY PENALTIES.—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) (other than subsections (a) and (b) of such section) shall apply to a civil money penalty described in paragraph (2)(B) in the same manner as such section applies to a penaltry or proceeding under subsection (a) of such section.

(i) SUSPENSION, REVOCATION, AND LIMITATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), the license of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of

the laboratory, that such owner or operator or any employee of the laboratory—

(A) has been guilty of misrepresentation in obtaining the license;

(B) has performed or attempted to perform or represented the laboratory as entitled to perform a laboratory procedure or category of procedures not authorized in the license;

(C) has failed to comply with the standards with respect to laboratories prescribed by the Secretary under subsection (f);

(D) has failed to comply with reasonable requests of the Secretary for any information or materials, or work on materials, the Secretary consider necessary to determine the laboratory's continued eligibility for its license or continued compliance with the Secretary's standards;

(E) has refused a request of the Secretary or any Federal officer or employee duly designated by the Secretary for permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation; or

(F) has violated or aided and abetted in the violation of this section or of any regulation promulgated under this section.

(2) SUSPENSION WITHOUT HEARING.—If the Secretary determines that the failure of a laboratory to comply with the standards of the Secretary under subsection (f) presents an imminent and serious risk to human health or if a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1), the Secretary may suspend the license of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 4 months from the effective date of the suspension. A suspension under this paragraph shall stay in effect until the decision of the Secretary made after the hearing under paragraph (1).

(3) INELIGIBILITY TO OWN OR OPERATE LABORATORIES AFTER REVOCATION.—No person who has owned or operated a laboratory that has had its license revoked may, within 2 years of the revocation of the license, own or operate a laboratory. The license of a laboratory under this section that has been excluded from participation under the medicare program established under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(j) INJUNCTIONS.—Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to public health, the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. On a proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

(k) JUDICIAL REVIEW.—

(1) PETITION.—Any laboratory that has had its license suspended, revoked, or limited by any final action taken under subsection (i) may at any time within 60 days after the date of such action file a petition with the United States court of appeals for the circuit in which the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

(2) ADDITIONAL EVIDENCE.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be adduced on the hearing in such manner and on such terms and conditions as the court may consider proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken. The Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the original action of the Secretary, with the return of such additional evidence.

(3) JUDGEMENT OF COURT.—On the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) FINALITY OF JUDGEMENT.—The judgement of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States on certiorari or certification as provided in section 1254 of title 28, United States Code.

(l) SANCTIONS.—

(1) IN GENERAL.—Any person who willfully violates any provision of this section or any regulation promulgated under this section shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than 1 year, or a fine of not more than $10,000, or both such imprisonment and fine, except that if a person commits such a violation after a conviction under this paragraph has become final, such person shall be imprisoned for not more than 3 years or fined not more than $100,000, or both.

(2) USE OF SPECIMENS PRODUCED BY UNLICENSED LABORATORIES.—Any person who solicits or accepts, directly or indirectly, a specimen knowing that a laboratory test or other laboratory procedure will be performed using such specimen by a laboratory that is required to have in effect a license issued under this section and that does not have such a license in effect, or that

is not authorized by its license to perform such test or procedure, shall be subject to a fine of not more than $100,000, or imprisonment for not more than 1 year, or both.

(3) FALSE STATEMENTS.—Any person who willfully engages in any false, fictitious, or fraudulent statement in order to obtain or maintain a license under this section or to prevent discovery of a violation of this section shall be subject to a fine of not more than $100,000 or imprisonment for not more than 1 year, or both.

(m) FEES.—

(1) IN GENERAL.—The Secretary shall require payment of fees for the issuance and renewal of licenses and fees for laboratory inspections, in such amounts as the Secretary may establish to carry out this section.

(2) LICENSE FEES.—License fees imposed under paragraph (1) shall be sufficient to cover the costs of administering this section, including evaluating and monitoring approved proficiency testing programs and accrediting bodies, implementing and monitoring compliance with the requirements of this section, and fulfilling the reporting requirements of this section. The license fees shall be based on the dollar volume and scope of the testing being performed by the laboratory.

(3) INSPECTION FEES.—Inspection fees imposed under paragraph (1) shall be sufficient to cover the costs of inspections conducted by the Secretary for laboratories that are not accredited by an approved accrediting body or licensed by an exempt State. Laboratories that are accredited by an approved accrediting agency, or licensed by an exempt State, shall not be required to pay the inspection fees, but shall be required to pay the license fees.

(n) INFORMATION.—On April 1, 1990, and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year, that the Secretary determines is useful in evaluating the performance of a laboratory, including—

(1) a list of laboratories that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

(2) a list of laboratories—

(A) that have had their licenses revoked, suspended, or limited under subsection (i); or

(B) that have been the subject of a sanction under subsection (l);

together with a statement of the reasons for the revocation, suspension limitation, or sanction;

(3) a list of laboratories subject to intermediate sanctions under subsection (h);

(4) a list of laboratories against which the Secretary has taken action under subsection (j), together with a statement of the reasons for such action; and

(5) a list of laboratories that have been excluded from participation under title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 et seq.).

The informaiton to be compiled under pragraphs (1) through (5) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such information as is necessary to interpret the information compiled under such paragraphs.

(o) DELEGATION.—In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay for the services or facilities in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

(p) STATE LAWS.—

(1) IN GENERAL.—Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

(2) MORE STRINGENT REQUIREMENTS.—If a State enacts a law relating to a matter covered by this section that provides for a requirement equal to or more stringent than a requirement of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.

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